UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,989	04/06/2004	Peter Unger	B0280US01	2988

24994 7590 08/20/2007

GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER	
MUI, CHRISTINE T	
ART UNIT	**PAPER NUMBER**
1709	

MAIL DATE	DELIVERY MODE
08/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/708,989	UNGER ET AL.	
	Examiner	Art Unit	
	Christine T. Mui	1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06 April 2004; 15 April 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show 8' in Figure 8 in [0059] and 8 in Figure 8 in [0060] as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the

description: 41 in Figure 8. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: in [0017] in the instance where it reads "the medical fluid is positively sucked analysis device" should read "the medical fluid is positively sucked into the analysis device".

Appropriate correction is required.

Claim Objections

4. Claim 3 is objected to because of the following informalities: In claim 3, line 3, in the instance where it reads "gible pin. or membrane, or by opening a valve" should read "gible pin, membrane, or by opening a valve". Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 9-10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,863,454 to LaBove et al. (herein referred "LaBove").

7. Regarding claim 1, the reference LaBove discloses a method and apparatus for preparation and delivery of an intravenous therapeutic agent that minimizes the possibility of contamination, exposure and improper dosage level of a drug. One container, preferably flexible bags of a plastic capable of maintaining a sterile environment, is pre-filled with a diluent and another container is filled with a dry form of a drug. The containers are joined with a flow connector between them, which allows the diluent to flow into the drug container for mixing (see abstract, column 3, lines 30-31).

8. Regarding claim 2, the reference LaBove discloses a tubular connector 18 that attached at one end of a discharge portal 16 of one container and has a stop cock assembly 20 disposed in about the center of the connector 18 (see column 3, lines 46-49; Figure 1).

9. Regarding claims 3 and 5, the reference LaBove discloses the stop cock assembly 20 disposed in about the center of the connector 18 is shown in a closed position in Figure 1. At the time desired to make the intravenous mixture the stop cock 20 is rotated to the open position and diluent in the container 10 flows into the container 22 through the connector 18 (column 3, line 52 and column 4, lines 2-5; Figure 1). It is interpreted by the examiner that the stop cock functions as a valve to allow fluid communication between the fluid bag and analysis device.

10. Regarding claim 4, the reference LaBove discloses another embodiment of the apparatus where the stop cock assembly 88 has an injection spike 90 with a lumen 92 through the center. The injection spike is made of a rigid material where it is firmly inserted through a diaphragm in a discharge portal 78 when the dual bag system is ready for use (see column 5, lines 12-17; Figure 3). It is interpreted by the examiner that the diaphragm in the discharge portal 78 functions as a membrane.

11. Regarding claim 9, the reference LaBove discloses a dual bag system where a first container 10 is in connection with a second container 22 by means tubular connector 18. One of the containers is pre-filled with a diluent and the other is pre-filled with a dry form of a drug or therapeutic agent (see abstract and column 3, lines 34-56; Figure 1).

12. Regarding claim 10, the reference LaBove discloses a stop cock assembly 20 in the tubular connector 18 that is used to instigate flow between the two chambers is desired (see column 3, lines 46-48 and column 4, line 2-4). It is interpreted by the

examiner that the stop cock, when in a closed position, is a blocking device arranged in the connection tube, preventing flow from one container to the other.

13. Regarding claim 12, the reference LaBove disclose in another embodiment of the apparatus, the stop cock assembly 88 has an injection spike 90 with a lumen 92 through the center where the injection spike is made of a rigid material. When the injection spike 90 is firmly inserted through a diaphragm in the discharge portal 78 mixing occurs between the dual bag system (see column 5, lines 12-16; Figure 3). It is interpreted by the examiner that the diaphragm between the two bags functions as a membrane as a thin pliable sheet of material.

14. Regarding claim 13, the reference LaBove discloses the two containers are in connection by a tubular connector 18 where a stop cock assembly 20 is disposed in about the center of the connector 18 (see column 3, lines 46-49). It is interpreted by the examiner that the stop cock functions as a valve, controlling the flow the liquid or flow between the containers or bags.

15. Claims 1-3, 5, 7, 9-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 6,372,182 to Mauro et al. (herein referred "Mauro").

16. Regarding claim 1, the reference Mauro discloses a single integrated device where a body fluid of a human or animal can be both collected and analyzed easily and without risk of contamination (see abstract). The body fluid is collected in a collection pouch that is preferably made from a flexible, transparent or translucent polymeric material so that the amount of blood present in the pouch can be easily manipulated.

The collection pouch is integrated with a transfer unit by a conduit and an analysis unit where the blood is filtered and flows through an analysis unit that may have a chemical, monoclonal or other constituents to detect the presence of antibodies to the HIV virus (see column 5, lines 18-22, 29-30 and column 6, lines 25-29, 34-36 and 46-49).

17. Regarding claims 2-3, the reference Mauro discloses that the mechanism for transferring the blood sample from the blood collection pouch to the analysis until is the transfer unit which allows a precise amount of the blood sample to be withdrawn from the pouch and transferred to the analysis until without loss or contamination. The transfer unit is connected to the pouch by a conduit, which terminates in a one-way valve to the analysis unit that is permanently connected (see column 8, lines 21-31 and 60-63).

18. Regarding claim 5, the reference Mauro discloses that in order to initiate flow from the pouch to the analysis unit, the operator squeezes the flexible pouch to flow the sample of blood through the one way valve, which opens the path for the flow the blood into a chamber that flows eventually into the analysis unit (see column 9, lines 14-20).

19. Regarding claim 7, the reference Mauro discloses in determining the presence or absence of the predetermined component in the analysis unit, there are in each of the sensors may be indicated in a variety of different ways, most of which involve the use of a visual indicator which appears or fails to appear during the analysis. When the blood flows through the unit and the component is not present, there is no reaction with the treating chemical and the treated area remains clear without the appearance of a pattern or the original "unreacted" color. If the blood sample does contain the desired

component, a reaction between the component and the detecting substance occurs and the color of the treated area changes substantially in color and/or a distinctive pattern appears on the substrate. The new color and pattern are visible through the transparent portion of the sensor on the housing of the analysis unit (see column 6, lines 59-66 and column 7, lines 8-18).

20. Regarding claim 9, the reference Mauro discloses a single integrated device where a body fluid of a human or animal can be both collected and analyzed easily and without risk of contamination (see abstract). The device has a body fluid collection pouch that is integrated with a transfer unit that is connect by means of a conduit into a an analysis unit with a housing. At the opposite end of the conduit in the transfer unit where there is an inlet into the flow path of the analysis unit, containing a chemical, monoclonal or other constituents to detect the presence of antibodies to the HIV virus, where it is constructed of an opaque plastic or metal with a series of holes in it with each hole alighted with an analysis or control unit where the color or pattern change can be visibly observed for the presence or absence of a specific component (see column 5, lines 19-23 and 30-31, column 6, lines 46-49 and 59-67, column 7, lines 8-18).

21. Regarding claims 10 and 13, the reference Mauro discloses that the transfer unit connecting the blood fluid collection pouch and the analysis unit are connected by a conduit which terminates in a one-way valve allowing blood to only flow "downstream" in the direction from the pouch to the analyzer. There is no backflow or "upstream" flow of the blood permitted through the valve ensuring that no blood, which is extracted from the pouch, is allowed to return (see column 8, lines 21-36).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaBove as applied to claim 2 above, and further in view of USP 5,258,314 to Skerratt (submitted on the Information Disclosure Statement on 15 April 2004, herein referred "Skerratt").

26. Regarding claim 6, the reference LaBove discloses the claimed invention except for arranging a cassette surround the air pocket. Skerratt discloses a microprocessor-based biomedical monitoring apparatus where a roller assembly pulls a compartmentalized pouch through the apparatus until it blocks the optosensors for detection (see column 3, lines 37-38, 57-60; Figure 2). It is interpreted by the examiner that the roller assembly that pulls the pouch through the apparatus and surrounds the pouch is considered as a cassette that applies a pressure to push fluid from one compartment of the pouch to the other. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a cassette surrounding the bag or pouch to exert pressure to initiate flow between compartments of the pouch or into a separate pouch that is connected by a tubular connector to instigate mixing of fluids or reagents.

27. Claims 7 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaBove as applied to claim 1 above, and further in view of and further in view of DE 3504527 A1 to Gropp et al. (submitted on the Information Disclosure Statement on 15 April 2004, herein referred "Gropp").

28. Regarding claim 7, the reference LaBove discloses the claimed invention except for displaying a reaction of the reagent. Gropp discloses a urine collection bag with an indicator mechanism. The indicator mechanism is where colorforming reaction layer is formed to determine urine status regarding the blood and pH values (see page 1 of translation). It would have been obvious to one having ordinary skill in that art at the time the invention was made to have a displaying means such as a transparent bag or container to indicate the status of the specimen in the bag by the formation of a color layer.

29. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over LaBove and Gropp as applied to claim 7 above, and further in view of Skerratt.

30. Regarding claim 8, the reference LaBove and Gropp disclose the claimed invention except for an optical analysis apparatus arranged at the cassette means. Skerratt discloses a roller assembly that surrounds a pouch that applies pressure to the pouch to initiate flow between compartments of the pouch. The roller assembly pulls the pouch through the rollers until the pouch blocks the optisensors 27 (see column 3, lines 57-60). The optisensors are made up of a light source and light sensor that detects colorimetric analysis of the pouch in the roller assembly (see column 2, lines 38-47). It would have been obvious to one having ordinary skill in that art at the time the invention was made to construct the cassette means surrounding the pouch with a detecting or analyzing means within the system so that the pouch or bag can be immobilized while being analyzed.

31. Claim 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaBove as applied to claim 9 above, and further in view of Skerratt.

32. Regarding claim 14, the reference LaBove discloses the claimed invention except for a cassette surrounding the air pocket. Skerratt discloses a microprocessor-based biomedical monitoring apparatus, which comprises of a roller assembly that pulls a pouch though the assembly such that the pouch is disposed between the rollers in a slot (see column 3, lines 48-54). The pouch is pulled through the rollers in the assembly until it blocks the optosensor that detects changes in the pouch with a light source and sensor (see column 3, lines 58-60 and column 2, lines 44-48). It is interpreted by the examiner that the roller assembly functions as a cassette surrounding the pouch. It would have been obvious to one having ordinary skill in that art at the time the invention was made to construct a cassette around the pouch or bag used as a detecting means of the pouch during reactions or protection from high pressure that may break the pouch.

33. Regarding claim 16, the reference LaBove discloses the claimed invention except for the air pocket comprising of two plastic foils and where a reagent is coated on the inner surface of one of the foils. LaBove discloses the containers that are used are preferably made of flexible bags of a plastic capable of maintaining a sterile environment where one of the containers contains a dry form of a drug (see column 3, lines 30-31). Gropp discloses a urine collection bag with colorforming reaction layers on the bag to indicate individual components in urine (see page 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

construct the flexible bags of two plastic foils rather than a unitary piece of material where there are colorforming reaction layers on one of the foils to indicate components in a specimen or contamination of the specimen.

34. Regarding claim 17, the reference LaBove and Gropp disclose the claimed invention except for explicitly state that the air pocket is expandable where the maximum volume is larger than the volume of the air enclosed in the connection tube. LaBove discloses that the containers in the apparatus are preferably constructed of flexible bags of plastic capable of maintaining a sterile environment (see column 3, lines 30-31). It is interpreted by the examiner that the flexible plastic that the bags are constructed from are expandable when pressure is applied and upon squeezing, is capable of containing a volume that is larger than the volume of the fluid connector 18. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct expandable plastic bags to contain a specimen with a large maximum volume in the instance where pressure is applied to the bag, the bag is able to withstand pressure, when applied and expand without breaking.

35. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over LaBove as applied to claim 10 above, and further in view of USP 4,403,992 to Bertellini et al. (herein referred "Bertellini").

36. Regarding claim 11, the reference LaBove discloses the claimed invention except for the blocking device is a frangible pin. Bertellini discloses a continuous peritoneal dialysis bag device where the device has a flexible bag of plastic material

with two chambers, a liquid chamber and a disinfectant chamber, that are closed off at the inside of the chamber. The release of the closures in the chambers may be of a frangible pin that can be broken off by the flexible bag permitting removal of dialysis fluid and disinfectant from the respective chambers (see abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a frangible pin between two containers to permit the flow so that one can immediately allow mixing of reagents by flexing, squeezing or applying pressure to the bag.

37. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over LaBove as applied to claim 9 above, and further in view of USP 5,619,333 to Staff et al. (herein referred "Staff").

38. Regarding claim 15, the reference LaBove discloses the claimed invention except for an optical device for detecting the reaction of the analysis means. Staff discloses a portable on-line fluid contamination monitor where an optical sensor assembly used to view fluid that is withdrawn from a circuit and determine the level of contamination by observing the particles therein. The optical means for viewing the fluid is through a window by means of a light source disposed to project light through the window and a fluid and having a light sensor disposed on the opposite side of the window from the light source to detect particles in the fluid passing across the window by sensing the duration and extent of light obscuration caused by the particles in the fluid. The light sensor is preferably is a photodiode, but may be replaced with a charged coupled device (CCD) or other similar device (see abstract, column 2, lines 2-9, 66-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an optical sensing means to detect the reaction occurring in the container or bag or contamination by means of a light source and sensor or CCD to optically monitor changes in the container with analog signals.

Conclusion

39. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP 4,820,297 to Kaufman et al. and USP 5,702,383 to Giesler et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

Melvin Mayes
Primary Examiner
AU1734